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with his own clinical experience. As a medical doctor, his precautionary, “better safe than sorry” standard of causation renders his purported “differential diagnosis” fatally flawed. He provides literally no explanation or methodology for “ruling in” continuous infusion of local anesthetics via pain pump into the intra-articular joint (“continuous infusion”) as a potential cause of chondrolysis. His method for “ruling out” other potential causes is cursory and incomplete. In short, he has proffered nothing more than an “educated hunch” as his causation opinion, which finds no support in the published scientific literature. Dr. Davidson’s low threshold for a causation opinion may serve him well in the clinical setting, but it fails the *Daubert* standard for reliable, scientific evidence.

II. ARGUMENT

A. Overview

1. The *Daubert* Standard

“Expert opinions are about science.” *Nelson v. Tennessee Gas Pipeline Co.*, 1998 WL 1297690 at *9 (W.D. Tenn. Aug. 31, 1998)². “*Daubert*’s requirement that the expert testify to scientific knowledge – conclusions supported by good grounds for each step in the analysis – means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *Rose v. Matrixx Initiatives, Inc.*, 2009 WL 902311 at *10 (W.D. Tenn., Mar. 31, 2009)³. Thus, “the Sixth Circuit ... instructed courts to take a ‘hard look’ at the expert’s basis for his scientific opinion.” *Nelson*, 1998 WL 1297690 at *3.

“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Thus, “the district

² The entirety of the unpublished *Nelson* decision is attached to the Tucker Declaration at Exhibit B.

³ The entirety of the unpublished *Rose* decision is attached to the Tucker Declaration at Exhibit C.

court's paramount objective is to discern the reliability of a technique, theory, or procedure employed by the expert witness." *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205, 1208 (E.D. Tenn. 2000). "[C]lose judicial analysis of such technical and specialized matter is necessary not only because of the likelihood of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists." *Nelson*, 1998 WL 1297690 at *3.

Indeed, "[o]ne very significant fact" in assessing the bias or reliability of experts is "whether they have developed their opinions expressly for purposes of testifying. ... That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were derived by the scientific method." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("*Daubert II*"). Moreover, "[w]idespread acceptance can be an important factor in ruling particular evidence admissible" *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993) ("*Daubert I*"). "[W]hen an expert expresses an opinion which is not generally accepted within the medical and scientific communities, he has an obligation to provide a reasoned explanation of why his methodology and opinions differ from those representing the collective view of the relevant medical or scientific disciplines." *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1024 (S.D. Ohio 1992).

2. Dr. Davidson's Report

Dr. Davidson submitted an expert report in which he states his job is to "speak to the probable cause of post-arthroscopic glenohumeral chondrolysis in Mr. Rodriguez's right shoulder." [Davidson Rpt. at 2, Tucker Decl. Exh. D.] He also claims that he is relying on the scientific and medical literature attached to his report as Appendix A, but this is the first and last time it appears in his report. [*Id.* at 3.] He provides absolutely no explanation as to how that literature informs or supports his opinions. After acknowledging that his only experience with

continuous infusion and chondrolysis is limited to a single patient, he undertakes a 7-page recitation of Plaintiff's medical history, without analysis. At the conclusion, he merely states his impression that Plaintiff has chondrolysis, which he "relate[s] ... principally to the implantation of the pain pump from surgery November 15, 2004." [*Id.* at 10.] Nowhere does he explain the science, methodology, or rationale behind his implicit assumption that continuous infusion causes chondrolysis in general. He merely proceeds, pursuant to "differential diagnosis," to "rule out" other potential causes and conclude that Plaintiff's chondrolysis is "related to the infusion pump catheter placed on November 15, 2004." [*Id.* at 10-11.]

B. Dr. Davidson's opinion lacks key indicia of reliability because it is litigation-driven, contradicts his own clinical experience, and constitutes the educated hunch of a clinician – unsupported by a preponderance of the scientific evidence.

1. Dr. Davidson's opinion is litigation-driven.

Dr. Davidson's report discloses no prior research into continuous infusion or chondrolysis. In fact, the entirety of his experience at the intersection of these two topics appears to relate to a single patient he treated with continuous infusion who subsequently developed chondrolysis. [Davidson Rpt. at 3, Tucker Decl. Exh. D.] His involvement in this litigation stems, not from his independent scientific research, but from his pre-existing relationship with Plaintiff's counsel in this litigation. [Davidson Depo. at 12:8-17, Tucker Decl. Exh. E.] Indeed, Plaintiff's counsel has played a very prominent role in Dr. Davidson's involvement in this litigation, from paying him approximately \$200,000 for case reviews to directing the content of his reliance literature. [*Id.* at 11:21-12:2, 46:8-17.] The litigation impetus for his opinion is a "very significant fact" that cuts against Dr. Davidson's reliability. *Daubert II*, 43 F.3d at 1317. That an expert has developed his opinions expressly for the purpose of testifying is "the most persuasive basis" for concluding that his opinions were not derived by the scientific method. *Id.* Dr. Davidson thus begins the *Daubert* analysis at a significant disadvantage that cannot be erased

or even mitigated by his assurance that his opinions are held “within a reasonable degree of medical probability,” whatever that is. [Davidson Rpt. at 3, Tucker Exh. D.] “The ipse dixit of the expert alone is not sufficient to permit the admission of an opinion.” *Tamraz*, 2010 WL 3489002 at *5 (holding “it makes no difference” that expert purported to find causation “with a reasonable degree of medical certainty”).

2. Dr. Davidson’s own clinical experience is directly contrary to his opinion.

Adding to Dr. Davidson’s reliability deficit is the tremendous disconnect between his assumption that continuous infusion causes chondrolysis and his own clinical experience on that front. His report states that he has had only one of his patients develop chondrolysis, and that patient had received continuous infusion. [Davidson Rpt. at 3, Tucker Decl. Exh. D.] His report fails to mention, however, that he was treating between 50 and 75 patients a year with continuous infusion between 2004 and 2007. [Davidson Depo. at 53:21-54:11, Tucker Decl. Exh. E.]

Even allowing for the fact that he “diminished the use” in 2007 (and attributing a 50% drop in volume to that diminishment), Dr. Davidson therefore treated somewhere between 175 and 262 of his own patients with continuous infusion, yet only a single patient subsequently developed chondrolysis. [*Id.* at 54:12-21, 55:21-56:3.] Thus, in his own extensive experience with continuous infusion, well under 1% of his patients developed chondrolysis ($1/262 = 0.38\%$; $1/175 = 0.57\%$). Yet, as a paid expert for Plaintiff, Dr. Davidson is willing to opine that it is “medically probable” that Plaintiff’s continuous infusion caused his chondrolysis. [Davidson Rpt. at 3, 11; Tucker Decl. Exh. D.]

Such a jarring juxtaposition might not be fatal to Dr. Davidson’s reliability, had he acknowledged the discrepancy between his opinion and his experience and set forth the scientific reasoning that allowed him to discount the latter in favor of the former. *Rose*, 2009 WL 902311 at *10 (*Daubert* requires “conclusions supported by good grounds for each step in the analysis”).

But his report contains no explanation at all of the scientific basis for his assumption that continuous infusion causes chondrolysis. This failure to account for evidence that directly contradicts his opinion and suggests a host of other factors at play is a fatal flaw that requires exclusion under *Daubert*. *Nelson*, 1998 WL 1297690 at *11 (excluding expert who “discounted other factors with no explanation whatsoever”).

3. Dr. Davidson’s opinion is based on the precautionary “educated hunch” of a clinician, not scientific proof of causation.

Dr. Davidson willingness to opine that continuous infusion causes chondrolysis when, in his own experience, greater than 99% of his patients never develop it, betrays a clinician’s standard for causation, not a scientist’s. “[M]ost treating physicians have more training in and experience with diagnosis than etiology.” *Tamraz*, 2010 WL 3489002 at *7. The emphasis on diagnosis stems from the Hippocratic Oath at the core of their profession: First, do no harm. As the Sixth Circuit put it, “[g]etting the diagnosis right matters greatly to a treating physician, as a bungled diagnosis can lead to unnecessary procedures at best and death at worse.” *Id.* It is therefore critical to patient safety that a physician’s diagnosis be accurate and precise. But that same concern for patient safety requires physicians to assume causation even when it is not scientifically proven. By employing this “precautionary principle” when it comes to etiology, physicians can advise and treat patients in ways that safeguard their health based solely on “educated hunches,” without having to wait for and scrutinize scientific proof of causation. *Id.* “This low threshold for making a decision serves well in the clinic but not in the courtroom, where a decision requires not just an educated hunch but at least a preponderance of the evidence.” *Id.*

Dr. Davidson has done the same thing here. He has set forth no scientific methodology for his determination that continuous infusion causes chondrolysis. He has not explained whether or how the literature he cites can be extrapolated to support his determination. The

Court is left only with his assumption of general causation. That his assumption is premised upon a clinician's low threshold is apparent from his deposition testimony. When presented with the Lo article's conclusion that "the relative safety of a single dose or continuous infusion of local anesthetics is unclear," Dr. Davidson disagreed, though he conceded that "[t]here are still unanswered questions." [Davidson Depo. at 67:22-68:18, Tucker Decl. Exh. E.] His rationale: "I think the safety in the shoulder at this point was questioned to such an extent where there were leaders in the orthopedic field that had specifically recommended against it." [*Id.*] In other words, it does not matter to Dr. Davidson's opinion that the safety of continuous infusion is still a matter of scientific debate; what matters is that it is sufficiently suspect to recommend against its use. This position is appropriate and admirable from a clinician. From a scientific expert, it fails *Daubert*'s standard for scientific causation evidence. *Tamraz*, 2010 WL 3489002 at *7 ("This low threshold for making a decision serves well in the clinic but not in the courtroom, where a decision requires not just an educated hunch but at least a preponderance of the evidence.").

C. Dr. Davidson's "differential diagnosis" is fatally flawed because it fails reliably to "rule in" the potential causes of chondrolysis or "rule out" the rejected causes.

Dr. Davidson seeks to ease anxiety about the reliability of his causation opinions by invoking "differential diagnosis" as his methodology. "Differential diagnosis is the method by which a physician determines what disease process caused a patient's symptoms", not what outside influence caused the patient's disease process. *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 178 (6th Cir. 2009). In any event,

[s]imply claiming that an expert used the differential diagnosis method is not some incantation that opens the *Daubert* gate. Calling something a 'differential diagnosis' or 'differential etiology' does not by itself answer the reliability question but prompts three more: (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the

possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the court answers “no” to any of these questions, the court must exclude the ultimate conclusion reached.

Tamraz, 2010 WL 3489002 at *8.

It is debatable whether Dr. Davidson has accurately diagnosed chondrolysis in this case. Plaintiff’s second treating surgeon, Dr. Sean Kaminsky, thought it “probably unlikely” that Plaintiff had developed chondrolysis by 2008, because the arthritic changes to his shoulder joint were insufficiently rapid and diffuse. [Kaminsky Depo. Vol. 2 at 76:17-80:1, Tucker Decl. Exh. F.] But even assuming Dr. Davidson has accurately diagnosed Plaintiff’s condition, he fails reliably to rule in continuous infusion as a potential cause of chondrolysis, just as he fails reliably to rule out the potential causes he rejects.

1. Dr. Davidson’s fails reliably to “rule in” the potential causes of chondrolysis.

a. Dr. Davidson provides literally no explanation or insight into his implicit opinion that continuous infusion can cause chondrolysis; mere listing of articles is insufficient.

In order to reach his conclusion that continuous infusion caused Plaintiff’s case of chondrolysis, Dr. Davidson must have concluded – or assumed – that continuous infusion causes chondrolysis in general. *See Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 874 (S.D. Ohio 2010) (“General causation establishes whether the substance or chemical at issue is capable of causing a particular injury or condition in the general population. ... Specific causation establishes whether the substance or chemical in fact caused the plaintiff’s medical condition”). General causation is typically demonstrated through a review of the pertinent scientific and medical literature. *In re Welding Fume Prods.*, 2005 WL 1868046 at *32 n.73 (N.D. Ohio Aug. 8, 2005)⁴. Dr. Davidson offers no such demonstration. Though he appends to his report a list of

⁴ The entirety of the unpublished *In re Welding Fume Prods.* decision is attached to the Tucker Declaration at Exhibit G.

literature upon which he purports to rely, he has offered no explanation or analysis as to how the literature supports a scientific conclusion that continuous infusion causes chondrolysis.

[Davidson Rpt. at 3, Tucker Decl. Exh. D.]

An appended list of unexplained literature is patently insufficient. *Nelson*, 1998 WL 1297690 at *11 (excluding expert because he “offered no insight [] into the reasoning process which led him from his opinion that the plaintiffs suffered from neurological impairments to the opinion that exposure to PCBs was the cause thereof.”). “A mere listing of numerous articles falls short of a reasoned scientific analysis of the methods by which the expert formulated his opinions from the publications cited.” *Id.* at *12. Dr. Davidson’s failure to explain the logical steps he took from his literature list to the general causation conclusion he reached renders his opinion unscientific and therefore excludable under *Daubert*. *Conde*, 804 F. Supp. at 1023-24 (“It is not a medical or scientific methodology to lump together without explanation [various literature] and then to assert without further analysis that these studies and other information about the toxicity of chlordane ‘caused’ symptoms and diseases.”); *Rose*, 2009 WL 902311 at *10 (“*Daubert*’s requirement that the expert testify to scientific knowledge – conclusions supported by good grounds for each step in the analysis – means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.”).

b. The articles Dr. Davidson cites do not support his general causation opinion.

Even more fundamentally, the literature Dr. Davidson cites does not support the conclusion that continuous infusion causes chondrolysis. Some of the articles are inherently unreliable scientific proof of causation. Others, while providing a quantum of scientifically cognizable knowledge, require scientific extrapolation to be reliable evidence herein. Even if such extrapolation were possible, which the authors deny, Dr. Davidson has failed to provide it here.

Of the 16 articles Dr. Davidson cites, 6 are case reports [Hansen (2007), Levy (2008), McNickle (2009), Rey (2009), Warne (2009), and Good (2007); Tucker Decl. Exhs. H - M]. Case reports “simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.” *Downs v. Perstorp Components, Inc.*, 126 F. Supp. 2d 1090, 1126 (E.D. Tenn. 1999). As a result, “case reports are not reliable scientific evidence of causation.” *Id.*

Another 2 are podium presentation abstracts [Scheffel (2009), Anderson (2008); Tucker Decl. Exhs. N - O], in which physicians briefly summarize the contents of their medical conference presentations. These abstracts “are not subject to peer review and as a result do not receive the scrutiny of the scientific community that confers an element of reliability on published [scientific research]. *Hazlehurst v. Dept. of Health & Human Svcs.*, 88 Fed. Cl. 473, 488 (Fed. Cl. 2009) (upholding special master’s determination that poster presentation was “preliminary, unpublished, and not entitled to substantial weight” and noting expert testimony that “such abstracts often turn out to be wrong”). They therefore do not constitute reliable scientific evidence of causation either. Neither does the single editorial he cites, which is by definition an opinion piece. [Lubowitz (2009); Tucker Decl. Exh. P;] *Bargas v. Lee*, 317 F.3d 498, 502 n.5 (5th Cir. 2003) (holding an editorial is insufficient to establish scientific reliability).

Another 5 of his articles are in vitro studies [Chu (2006), Gomoll (2006), Karpie (2007), Chu (2008), Lo (2009); Tucker Decl. Exhs. Q-U], in which the cartilage from various animals or humans is harvested and exposed to stimuli in a laboratory setting. Such studies are not *per se* unreliable evidence of causation in humans. However, any reliability they do possess is contingent upon a scientific explanation of how the varying doses of local anesthetics given to in vitro cells would permit a jury to conclude that continuous infusion more probably than not

causes chondrolysis in humans. *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1360-61 (6th Cir. 1992). Such an explanation is precluded here, however, because the authors of each of the studies cited caution against direct extrapolation of their findings to human experience. [Chu (2006) at 698 (“Clinical study would be required to determine clinical effects”), Gomoll (2006) at 817 (“[I]t remains to be determined whether human cartilage is equally susceptible”), Karpie (2007) at 1626 (“[I]n vitro results cannot be directly extrapolated to in vivo situations”), Chu (2008) at 820 (“[I]n vitro results cannot be directly extrapolated to clinical practice”), Lo (2009) at 714 (“these results may not be generalizable to large human joints”); Tucker Decl. Exhs. Q-U.] And, in any event, Dr. Davidson has failed to provide any explanation at all, let alone a scientifically reliable one. As a result, “[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue ... is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.” *Turpin*, 959 F.2d at 1360-61.

Finally, Dr. Davidson cites two articles by Dragoo. [Dragoo (2008), Dragoo (2010); Tucker Decl. Exhs. V-W.] Aside from the extrapolation problems they pose as set forth above, these articles not only fail to support his opinion on general causation, they actually suggest that the continuous infusion received by Plaintiff did not cause his chondrolysis. Plaintiff’s pain pump infused no more than 120 mL of 0.5% bupivacaine without epinephrine for 48 hours. [Kuhn Depo. at 42:2-45:11, Tucker Decl. Exh. X.] Dragoo (2008) found that 0.5% bupivacaine without epinephrine for 48 hours was not chondrotoxic, let alone caused chondrolysis, and he did not even recommend against its use. [Dragoo (2008) at 1484, Tucker Decl. Exh. V.] This is particularly problematic to Dr. Davidson’s opinion because Dragoo finds support in an article by Rapley, which found no chondrolysis in a group of patients whose shoulder joints were infused with 0.5% bupivacaine without epinephrine by pumps very similar to Plaintiff’s. [Rapley (2009)

at 1372, Tucker Decl. Exh. Y.] Dr. Davidson testified that he reviewed Rapley briefly, but he failed to address it in his report. [Davidson Depo. at 100:4-103:13, Tucker Decl. Exh. E.] Dragoo (2010) dealt solely with local anesthetics containing epinephrine, and thus had nothing to say about the potential causes of Plaintiff's condition, since his local anesthetic contained no epinephrine. [Dragoo (2010) at 1154, Tucker Decl. Exh. W.] Dr. Dragoo's research undermines Dr. Davidson's opinion, rather than supporting it.

2. Dr. Davidson fails reliably to "rule out" the potential causes of chondrolysis that he rejects.

In order to have performed a reliable "differential diagnosis," Dr. Davidson must have reliably ruled out the potential causes of chondrolysis that he has rejected. *Tamraz*, 2010 WL 3489002 at *8. There are at least five potential causes, however, that Dr. Davidson either failed to consider entirely, or dismissed without adequate explanation. This bare fact renders his "ruling out," and thus his differential diagnosis, unreliable. That Plaintiff actually manifested three of those potential causes makes Dr. Davidson's unreliability all the more clear-cut.

Dr. Davidson failed entirely to consider loose suture material, irrigation solutions, and trauma as potential causes of chondrolysis. Dr. Davidson acknowledges that suture material has been associated with chondrolysis and that loose suture material in the joint can cause cartilage damage. [Davidson Depo. at 94:7-21, Tucker Decl. Exh. E.] He also acknowledges that the sutures placed by Plaintiff's surgeon during his November 15, 2004, shoulder operation had come loose by 2006 and were embedded in the axillary pouch⁵. [*Id.* at 108:12-109:10.] Yet despite Plaintiff manifesting a potential cause of chondrolysis, Dr. Davidson never identified or discussed it in his report's consideration of alternative causes.

⁵ Dr. Davidson apparently did not realize, however, that the "loose body" that Dr. Kaminsky removed from Plaintiff's shoulder in 2006 was, in fact, the loose suture material, next to which Dr. Kaminsky found cartilage corrosion. *Cf.* [Davidson Depo. at 86:16-21, Tucker Decl. Exh. E] *with* [Kaminsky Depo. Vol. 1 at 39:13-40:5, 41:16-42:1; Tucker Decl. Exh. Z.]

Scientific research suggests that chondrocyte viability is affected by irrigation fluids, and in particular that hypo-osmolar solutions lead to decreased chondrocyte viability. [Solomon (2009) at 1337, Tucker Decl. Exh. AA.] Dr. Davidson clearly considers such studies relevant when they involve local anesthetics, because they figure prominently in his reliance literature. [Davidson Rpt. at App. A, Tucker Decl. Exh. D.] Yet in his report he ignores such studies without explanation when they involve irrigation solutions, and fails to consider whether such solutions had any impact on Plaintiff's condition. Similarly, Dr. Davidson agreed at his deposition that trauma was a possible cause associated with the development of chondrolysis. [Davidson Depo. at 64:20-65:9, *see also* Solomon (2009) at 1335; Tucker Decl. Exhs. E, AA.] Yet he fails to enumerate or discuss it in his report.

There are two more potential causes that Dr. Davidson raised – at least in part – in his report, but appears to have dismissed without good reason. First, “[p]re-existing cartilage degeneration or damage such as that seen in osteoarthritis or as a result of multiple recurrences of instability may further play a role in the development of chondrolysis.” [Solomon (2009) at 1335, Tucker Decl. Exh. AA.] Dr. Davidson acknowledged this in his deposition. [Davidson Depo. at 64:20-65:9, Tucker Decl. Exh. E.] His report, however, dealt only with the issue of inflammatory arthritis, and claims there was “no evidence of any joint surface or joint space damage indicative of antecedent inflammatory arthritis.” [Davidson Rpt. at 10, Tucker Decl. Exh. D.] At his deposition however, he acknowledged that Plaintiff had pre-existing arthritis in the same shoulder that later received the pain pump. [Davidson Depo. at 84:22-85:6, Tucker Decl. Exh. E.] At worst, Dr. Davidson's testimony is directly contradictory to his report, and indicates a myopic review of the arthritis issue that is clearly unreliable. But even at best, his testimony concedes that arthritis of any type, not only the inflammatory variety, is a potential cause of chondrolysis that Plaintiff manifested, but which Dr. Davidson completely ignored.

Finally, the discussion in Dr. Davidson's report regarding infection notes the presence of synovitis, but dismisses infection as a potential cause. [Davidson Rpt. at 10-11, Tucker Decl. Exh. D.] But at his deposition, Dr. Davidson admitted that he did not know if the synovitis in Plaintiff's shoulder was related to infection. [Davidson Depo. at 85:21-86:12, Tucker Decl. Exh. E.] This strongly suggests that the report's dismissal of infection as a potential alternative cause did not find a sound basis even within Dr. Davidson's own mind, which in turn throws the reliability of this determination in serious doubt.

D. Dr. Davidson's causation opinion is not generally accepted.

None of Dr. Davidson's articles claim that continuous infusion causes chondrolysis. The case reports affirmatively state that the etiology of chondrolysis is unknown. [Hansen (2007) at 1628 ("the cause of this process is unknown"), Levy (2008) at 380 ("The true etiology has yet to be identified."), McNickle (2009) at 1784 ("The causes of PAGCL have yet to be fully elucidated."), Rey (2009) at 98 ("Chondrolysis is a process of unknown etiology"), Warne (2009) at 42 ("No definitive ideology has been identified"), Good (2007) at 797.e1 ("Little is known about the pathophysiology of glenohumeral chondrolysis"); Tucker Decl. Exhs. H-M.] The in vitro studies, and even the editorial, limit themselves to statements about cyto- or chondro-toxicity, not chondrolysis. [Chu (2006) at 693; Gomoll (2006) at 813, Karpie (2007) at 1621, Chu (2008) at 814, Lo (2009) at 715, Dragoo (2008) at 1484, Dragoo (2010) at 1154, Lubowitz (2009) at 223; Tucker Decl. Exhs. Q-W.] The remaining articles refer only to associations and subjective beliefs, neither of which demonstrate causation as a matter of law. *In re Welding Fume Prods. Liab. Litig.*, 2005 WL 1868046 at *32 (study identifying an association did not demonstrate causation); *Tamraz*, 2010 WL 3489002 at *3 ("Because the 'knowledge' requirement of Rule 702 requires 'more than subjective belief or unsupported speculation,' the testimony should have been excluded."). There is quite literally not a single article, even

amongst Dr. Davidson's own cited literature, that reaches the general causation conclusion that he has, and many of them acknowledge that the cause of chondrolysis has yet to be determined.

It would be reasonable to assume that, if Dr. Davidson could not identify any literature that supported his opinion, it probably does not exist. But the Court need not extrapolate in this regard. Dr. Daniel Solomon recently conducted a comprehensive review of the scientific literature relating to post-arthroscopic glenohumeral chondrolysis ("PAGCL") in an attempt to determine its "potential contributors and causal pathways." [Solomon (2009) at 1329, Tucker Decl. Exh. AA.] Having reviewed 245 publications spanning nearly 50 years, he concluded:

[D]espite suggestions across existing case reports that certain factors appear to be correlated with PAGCL, without well-designed case-control studies that permit potential contributing factors of interest (i.e., exposures) to be examined in relation to PAGCL while adjusting for possible confounders, true risk factors for PAGCL cannot be identified, relative risks associated with the incidence of PAGCL cannot be established, causal inference is not possible, and sound practice and policy decision making will remain elusive at best.

[*Id.* at 1340-41 (emphasis added).] In other words, Dr. Davidson's conclusion that continuous infusion causes chondrolysis finds no support in the entirety of the scientific literature.

Widespread acceptance of an opinion is an important factor in determining its admissibility. *Daubert I*, 509 U.S. at 594. But here, Dr. Davidson's opinion not only lacks widespread acceptance, there is literally not a single published author willing to stand with him. This renders Dr. Davidson's outlier general causation opinion incompetent and excludable. *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 806 (N.D. Ohio 2004) (where expert opinion regarding general causation was unsupported by systematic review of clinical trials, it was "not competent for purposes of general causation"). Even if his opinion could find minority support within the literature, it would then be incumbent upon him "to provide a reasoned explanation of why his methodology and opinions differ from those representing the collective view of the

relevant medical or scientific disciplines.” *Conde*, 804 F. Supp. at 1024. But of course, here, as elsewhere, the Davidson report’s oft-lamented dearth of explanation prevents even that approach to reliability.

III. CONCLUSION

That Dr. Davidson’s opinions were engendered by this litigation and contradict his own clinical experience pose serious reliability deficits that few experts could overcome. But these pale next to his fundamental failure to explain the scientific basis for his conclusions. His opinions are essentially the educated hunches of a clinician, not the reliable conclusions of a scientist. Such hunches have their place in the clinic, but *Daubert* requires that the courtroom doors remain closed to them. Dr. Davidson’s opinions should be excluded in their entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2010, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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